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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

In re application of)	
Robert L. Lundak)	Examiner: J. Tarcza
Serial No. 247,656)	Art Unit: 172
Filed: March 26, 1981)	
For: HIGH FUSION FREQUENCY)	<u>APPEAL BRIEF</u>
FUSIBLE LYMPHOBLASTOID)	
CELL LINE)	

588-11

San Francisco, CA 94105

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Applicant appeals from the FINAL REJECTION of January 18, 1983 and the Advisory Action of May 9, 1983 finally rejecting Claims 1 and 2, the only claims of the subject application.

CLAIMS

1. An immortal B-cell line WI-L2-729HF₂.
2. A hybridoma resulting from the fusion of an immunized lymphocyte and a cell line according to Claim 1.

INVENTION

The subject invention is a novel human myeloma cell line which finds use as a fusion partner in the production of hybridomas which secrete human monoclonal antibodies. The cell line was developed from a known cell line which was subjected to repeated passages under certain specified conditions and the resulting colonies selected by their fusion efficiency. One clone was found to have a substantially elevated fusion efficiency and the cells were designated WI-L2-729HF₂. This is the subject matter of

Claim 1. The use of Claim 1 to produce hybridomas is the subject matter of Claim 2.

REJECTION

In the Final Rejection, Claims 1 and 2 were rejected under 35 USC 112 for failing to establish "permanent availability", citing a number of reasons for absence of proof of permanent availability of the subject cell line. A response was submitted on April 12, 1983 to the Patent Office providing for evidence that permanent availability was in fact provided for. It would appear that the evidence was satisfactory, since in the Advisory Action the objection was made that, "The objection to the specification as being non-enabling at the time of filing is maintained."

Claims 1 and 2 are stated to be free of the prior art.

QUESTIONS PRESENTED

The primary question before this Honorable Board is whether the application filed on behalf of Professor Lundak was enabling at the time of filing as required by Title 35 USC §112 ¶1. If not, whether the application should be accorded a subsequent date.

FACTS

On December 19, 1980, applicant's attorney was requested by the Office of the Board of Patents of the University of California to review a disclosure for patentability. An opinion was provided and on January 7, 1981, the U.C. Office authorized the attorney to begin preparation of an application. After receiving a disclosure from Professor Lundak on February 5, 1981, a proposed application was forwarded to the inventor on February 24,

1981, requesting Professor Lundak to review the application, if appropriate, return the executed application, and to deposit the subject cell line at the A.T.C.C.

Professor Lundak executed the application and requested his technician to expand the cell line so as to provide the necessary number of ampules to the A.T.C.C.

On March 23, 1981, applicant's attorney forwarded the executed application to his associate in Arlington, Virginia and requested her to file the application upon authorization, when it was confirmed that the cell line had been deposited at the A.T.C.C. On or about March 26, 1981, applicant's attorney was informed by Professor Lundak that the cell line had been forwarded to the A.T.C.C. and the associate was notified to file the application, which was promptly done.

Thereafter, Ms. Bobbie Brandon of the A.T.C.C. called applicant's attorney confused by a letter she had received from him concerning the subject cell line. She was unaware of any such cell line. Upon inquiry, Professor Lundak determined that the cell line had in fact not been sent to the A.T.C.C. The situation was promptly corrected and the necessary ampules sent to the A.T.C.C. and received by the A.T.C.C. on April 2, 1981. (See Bertram Rowland's Declaration of May 5, 1983, filed with the response dated May 5, 1983.)

From a time prior to the filing date of the application until the date of deposit of the cell line at the A.T.C.C., as well as thereafter, the subject cell line was maintained at three separate locations by members of the faculty of the University of California. Not only did the inventor, Professor Lundak, maintain a supply of the cell

line, but the cell line was also maintained by Drs. Bruce Devens and Richard Lubin, to ensure the permanent maintenance of the cell line and to protect against accidental loss. In addition, the cell line was also stored at the laboratory of Dr. John Lewis at the Loma Linda University Medical Center, where Dr. Lewis was characterizing the cell line. (See Professor Lundak's Declaration of March 23, 1983, filed with the response of May 5, 1983.) The cell line therefore has been maintained from a time prior to the filing of the application to the time of deposit at the A.T.C.C., and thereafter, by a number of different investigators at public institutions to ensure the continued maintenance and viability of the subject cell line.

The question devolves into two parts: (1) What is required in fulfilling the requirements of Title 35 USC 112 where the invention involves a unique cell line or microorganism? (2) Under the present set of facts, were the requirements of Title 35 USC 112 fulfilled?

ARGUMENT

Summary of the Argument

Under the applicable law, there is no requirement for deposit of an organism which is the subject matter of an application at the time of filing of the application. It is sufficient that the applicant provides assurance that the organism will be maintained in viable condition until a date at least later than the expiration of a patent issuing concerning such organism. In the event it should be decided that an organism should be deposited at the time of filing, then a filing date should be accorded applicant as of the

last act providing for a complete application as provided under 37 CFR §1.53 and §1.54.

In re Argoudelis et al., 168 USPQ 99 (CCPA 1971), as interpreted by Feldman v. Aunstrup, 186 USPQ 108 (CCPA 1975) clearly provided that the Argoudelis requirements as set forth in M.P.E.P. 608.01(p) are permissive and in any event may be retroactively satisfied by subsequent deposit under conditions fulfilling the Argoudelis requirements.

I. There Is No Statutory Basis For Requiring Deposit.

Title 35 USC 112 specifically provides for:

A written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. (emphasis added)

Therefore, the statute specifically prescribes "a written description," as the manner in which the invention is to be presented to the Patent and Trademark Office. However, concerning microorganisms, the Patent and Trademark Office believed it was faced with a peculiar problem. That is, where an essential element of an invention is within the control of the applicant, so that the invention cannot be practiced without such element, then at the expiration of the patent, the public will be deprived of practicing the invention and the patentee will have an unlawful extension of his monopoly.

While the problem is clear, the fact remains that the statute does not provide for the solution chosen by the Patent and Trademark Office. Clearly, in the case of plant patents (Title 35 USC 162), the statute specifically provided for noncompliance with §112. In the absence of

authorization by Congress, neither the Honorable Commissioner, nor the Courts, may specifically read out of the statute a clear and unambiguous requirement set forth in the statute. The description of the invention is to be "written," there is no latitude permitted for deposit.

Furthermore, there is no need for a requirement of deposit. If the Patent and Trademark Office believes that a sample will be necessary for the practice of the invention, the Patent and Trademark Office has the authority to request from the applicant a specimen as provided for under Title 35 USC 114.

Under the present system, the depositories are not part of the Patent and Trademark Office and do not look to the Patent and Trademark Office for authorization to supply the organism. Rather a contractual basis is required between the applicant and an independent entity. The deposit is then a matter of contractual law concerning third party beneficiaries which is properly regulated by the states. The effect is to transfer authority to state courts on an issue which should be solely reviewable by the C.A.F.C.

Nor is it seen that the organism should be supplied at the time of issuance of a U.S. Patent. The statute provides in Title 35 USC 271, "(a) except as otherwise provided in this Title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." §281 provides for a civil action against such infringer. No reason is seen why a patentee should aid and abet the infringement of his own patent. Yet, the Patent and Trademark Office would have the patentee

the unwilling accomplice to such infringing activity. While clearly the subject situation differs from the usual situation, where the teaching in a patent permits the independent reproduction of the information by the public, there is nothing in the statute which states that the public should have this benefit.

In effect, the U.S.P.T.O. would have a mandatory rule that the public must be capable of infringing on the date of issuance of U.S. Letters Patent. §271 is interpreted as designating a status which is a public right, rather than designating a status which allows for a civil remedy.

Lest it be considered that the public is deprived of any benefit upon publication of a patent concerning a microorganism, the fact of the existence of the microorganism, the properties it has, the manner of its use, and any other pertinent information, will provide the public with substantial useful information.

The only remaining question is whether the public can determine if it infringes the patent, where it has no direct comparison of its organism and the organism reported in the patent. So far as a unique naturally occurring organism, which is independently discovered by the public, there are many avenues which a member of the public could use to establish the presence of infringement. Refusal by the patentee to allow a comparison under reasonable circumstances could be interpreted as an estoppel against the patentee. Alternatively, as indicated above, the Patent and Trademark Office could require a specimen during the pendency of the application and release such specimen under

appropriate conditions to a member of the public, when the need arose.

These illustrations are merely provided to demonstrate that the present requirements of deposit go far beyond anything permitted by the statute and, furthermore, may be considered in violation of Title 35 USC 271(b) and (c) in the inducement and aiding and abetting of infringement. For these reasons, it is believed that the requirements set forth in In re Argoudelis, supra, should be withdrawn as violative of the statutory scheme for the filing and issuance of patent applications.

So far as the Budapest Treaty, Chapter 1, Article III(1)(a) is permissive and not mandatory concerning the need to deposit. The primary function of that Treaty is to create international depositories and provide for their regulation. In the absence of statutory authority, the permissive nature of the Budapest Treaty should not be read to modify the clear and unambiguous language of Title 35.

II. The Decisions Of The Appellate Tribunal Reject A Requirement Of Deposit At The Time Of Filing.

The last statement from the Courts and the Patent and Trademark Office concerning deposits is found in Feldman v. Aunstrup, 186 USPQ 110 (CCPA 1975), in which the Court affirmed the PTO Board of Interferences' finding of priority on behalf of Aunstrup. The issue was simply that Aunstrup had failed to deposit a microorganism at a depository consistent with the requirements set forth in Argoudelis and M.P.E.P. 608.01(p). The question before the Court was characterized as follows, 186 USPQ, at 111:

In support, Feldman argues that 'essentially none of the considerations *** in Argoudelis is present,' and that the Board erred in concluding

that the 'conditions' of the Commissioner's Notice of April 29, 1971, 8860.G.638 (now M.P.E.P. 608.01(p)), may be 'retroactively satisfied.'

The Court first established that the Argoudelis requirements are permissive, not mandatory. Clearly, in view of the earlier discussion, a mandatory requirement would be violative of the statute.

The Court in characterizing the §112 requirement of enablement stated, 186 USPQ, at 112:

However, the enablement requirement of §112, first paragraph, does not require such assured access to a microorganism deposit as of the filing date; what is required is assurance of access (to the microorganism culture by the public upon issuance of a patent on the application, prior to or during the pendency of the application, so that, upon issuance of a U.S. patent on the application 'the public will, in fact, receive something in return for the patent grant.'

The Court recited In re Argoudelis in support of this statement.

The Court read into the first paragraph of §112 that the public must be assured of having an essential starting material. They stated that this function is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date.

The Court referred to the decision in In re Hawkins, 179 USPQ 157 (CCPA 1973). In that decision, the Court, relying upon Argoudelis, stated, 179 USPQ, at 161:

As this writer pointed out in a specially concurring opinion in Argoudelis, the function of §112 in insuring complete public disclosure is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date. . . Further, for the satisfaction of the second aspect of §112--that of establishing the filing date as the prima facie date of invention--'it is essential that there be no question that, at the time an application for patent is filed, the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable

time, remain in order to obtain an operative, useful embodiment).'

The issue is squarely put that §112 requires that as of the filing date the applicant has solved all the problems necessary for the practice of his invention. The Court clearly states that as of the filing date it is not necessary that the public be able to practice the invention, it is sufficient that the applicant is able to practice the invention. The Court found that it is essential that at the time of issuance of the application as Letters Patent, the public be able to practice the invention. Regardless of the merits of this latter contention, the fact is that in accordance with the subject facts, the holdings of Feldman v. Aunstrup, and Hawkins are clearly complied with by the subject application.

First, all the technological problems concerned with the subject invention were solved as of the date of filing. The declarations by Professor Lundak and Mr. Rowland clearly establish that the cell line was extant on and before the date of filing of the subject application. Therefore, the technological problems associated with the subject cell line were solved, since the cell line which is the subject matter of the claims was extant and shown to be useful. Secondly, as evidenced by Professor Lundak's declaration, there was ample care taken to ensure the viability and continued existence of the subject cell line. Four different investigators, one of which was Professor Lundak, had possession of the cell line. Furthermore, the four investigators are investigators in public institutions, namely universities, where the individuals are familiar with the handling and maintenance of cell lines. Under these

circumstances, these individuals clearly are at least the equivalent of a foreign depository, which foreign depository was found acceptable in Feldman v. Aunstrup. Furthermore, the fact that a plurality of individuals had possession of the subject cell line at or before the filing date of the subject application clearly provides independent evidence of the existence of the cell line. Certainly, the dominion and control of Aunstrup over his cell line is not exceeded by the present fact situation.

Since the subject facts fall clearly in line with the decision in Feldman v. Aunstrup and in accordance with that decision, §112 requirements have been fulfilled, the subject application should be found as complete as of the date of filing.

III. Argoudelis Invidiously Discriminates Against A Particular Class Of Applicants.

It is well settled that an applicant has the right to file an application and obtain a constructive reduction to practice, where the application solves all the technological problems involved with the invention. The applicant need not have actually performed what is taught, so long as the description is complete and provides an enabling disclosure. Where an organism naturally exists and is isolated by the applicant, then in the absence of clairvoyance, one must assume that all technological problems have not been solved in obtaining such organism, unless such organism has actually been isolated and characterized.

By way of contrast, in the area of fusion partners for hybridomas, where a starting material is employed which is generally available, and procedures are described which

lead to a specific cell line having defined properties, there is no reason to believe that the process could not be repeated and a cell line having the same characteristics achieved. Thus, the situation is substantially different from the situation of the naturally occurring organism. While there is some uncertainty about the probability of obtaining a cell line which is identical to the cell line obtained by the applicant, nevertheless there should be no requirement that the applicant have a definite cell line, if the applicant believes that following his procedure will give a cell line having certain specific characteristics. Therefore, there seems no reason why applicants concerned with hybridomas should be uniquely limited in being denied a constructive reduction to practice.

So far as the "best mode" requirement, the working example need not be the best mode contemplated by the inventor. Having provided the best mode to obtain a cell line having the properties characterized by the applicant as his invention, this should be sufficient to fulfill the best mode requirement. There is apparently no need to require that the specific cell line developed by the applicant be available to the public or be established as existing at the time of filing of the application. The necessity for working examples for support has been repeatedly rejected by the Courts. In re Stephens, 188 USPQ 659 (CCPA 1976).

Finally, an extended patent fee schedule is provided in the statute under §41. There appears to be no discretion provided for the Commissioner in the charging of fees for the filing of a patent application. Yet, by requiring applicants to deposit organisms at depositories which are fee charging, the Commissioner is assessing an

additional fee for filing an application without statutory authority. It is submitted that the Honorable Commissioner may not do this and that if the Honorable Commissioner believes that there should be a deposit of organisms, to ensure the public's access to the such organisms, then the Commissioner may under §114 request such specimen and maintain the deposit at its own depository and cost.

IV. The Subject Application Should Be Granted The Date Of Deposit As Provided For In Title 37 CFR §1.53 and 1.54.

37 CFR §§1.53(b) and (e), 1.54(a) and 1.71(a)

state:

§1.53(b) The filing date of an application for patent is the date on which (1) a specification containing a description pursuant to §1.71 and at least one claim pursuant to §1.75, and (2) any drawing required by §1.81(a), are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date (§1.118).

§1.53(e) An application for a patent will not be placed upon the files for examination until all its required parts, complying with the rules relating thereto, are received, except that certain minor informalities may be waived subject to subsequent correction whenever required.

§1.54(a) It is desirable that all parts of the complete application be deposited in the Office together, otherwise a letter must accompany each part, accurately and clearly connecting it with the other parts of the application. See §1.53 with regard to completion of an application.

§1.71(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

It would seem clear that until a specification is provided the U.S.P.T.O. that fulfills the §1.71 requirements the application is incomplete. Where the incompleteness is

as a result of failure to deposit a microorganism at the time the application is submitted to the U.S.P.T.O., then upon deposit of the microorganism with the Argoudelis limitations, the application is complete. Based on the subject language of the regulations (as well as the predecessor language) it would appear that the filing date is the date of the last act to provide a complete application and not the date the written application is submitted to the U.S.P.T.O. Therefore, at the latest, applicant should be granted the date of deposit as his filing date.

V. Conclusion

Under the applicable law, applicant has fulfilled the requirements of §112. All technological problems concerned with the claimed invention had been solved as of the day of filing of the subject application. The fact is, that the cell line which is the subject matter of the subject application was extant as of that date and shown to be useful. Second, applicant had ensured that the cell line would be available at the time of issuance, by ensuring from the date of filing to the date of deposit, that the cell line was maintained in viable form. Third, the cell line was deposited in a manner to ensure the fulfillment of the requirements of Argoudelis prior to the issuance of the subject application. It is therefore submitted that the subject application is complete and fulfills the requirement of §112 and Claims 1 and 2 are allowable.

Despite the fulfillment of the requirements of §112, it is believed these requirements are contrary to the statute and should be withdrawn until statutory authority is obtained. The Argoudelis requirements are contrary to the

statute in depriving a particular class of applicants of a constructive reduction to practice; being contrary to the requirement of "written" description of the invention; and providing for the payment of additional fees which are not provided for in the statute.

Furthermore, the regulations set forth by the Commissioner allow for piecemeal filing of an application, where papers and parts may be incomplete. The filing date accorded is then the date of completion of the application. Under the above fact situation, the application should be accorded a date not later than the date of deposit at the A.T.C.C. in fulfillment of the Argoudelis requirements.

Finally, in view of the above fact situation, it is believed that the Honorable Commissioner should have accorded the subject application a date not later than the deposit date of the subject cell line. The Courts have permitted numerous applicants to correct errors in their application, where the errors were inadvertant and hardship occurred due to the errors. This fact situation exists here and the Honorable board is requested to rectify the situation by recognizing applicant's legitimate right to the filing date of the application or a filing date accorded not later than the date of deposit of the cell line.

In view of the above remarks, it is believed that the Examiner is in error in rejecting Claims 1 and 2 under §112 for failing to have an enabling disclosure. The Honorable Board is respectfully requested to reverse the Examiner and allow Claims 1 and 2.

Three copies of this Appeal Brief are provided, as well as the appropriate fee. [No oral hearing is requested.]

Respectfully submitted,

TOWNSEND and TOWNSEND

Date 9/14/83

By Bertram I. Rowland
Bertram I. Rowland
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BIR/gs
Enclosures

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 9/14/83
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